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EXAMINER	
WOOLWINE, SAMUEL C	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/743,991	CONNOLLY, D. MICHAEL	
	Examiner	Art Unit	
	SAMUEL WOOLWINE	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 December 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30 and 38-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-30 and 38-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/10/2007 has been entered.

Status

Claims 1-30 and 38-45 are pending in the application (claims 38-45 newly added).

All rejections under 35 USC 103(a) made in the final Office action of 06/11/2007 are withdrawn in view of Applicant's amendment to claim 1. The disclosure of Eichen et al (WO 99/57550) does not discuss a plurality of reactant chambers or transferring reagents from said reactant chambers to the detection chambers.

In addition, claim 9 was previously indicated as allowable subject matter (OA 06/11/2007). Upon further examination, prior art was found rendering claim 9 obvious.

New grounds of rejection are set forth below.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-30 and 38-45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites "storing reactants in other chambers". It is unclear whether "other chambers" refers to the aforementioned "plurality of reactant chambers" or to some "other chambers". Claims 2-30 and 38-45 depend from claim 1 and are rejected for the same reason. Applicant may obviate this rejection by replacing "other chambers" with "said plurality of reactant chambers".

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 38-41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a NEW MATTER rejection.

Applicant's disclosure at paragraph [0012] recites: "A consignment of merchandise can be checked at any point during shipping and a definitive determination of its authenticity made 15-30 minutes after sampling." However, the claims recite specific time intervals *between the steps of pumping the reactants into the detection chamber [and] the detecting of target nucleic acid present*. This is not the same as

between *sampling* and detection. Furthermore, even if Applicant amends to recite the time interval between pumping reactants and detection, claims 39 and 41 would still be considered new matter, because the disclosure only supports a time interval from 15 to 30 minutes. Claim 39, however, recites "no more than sixty minutes", which encompasses times outside the supported range. Similarly, claim 41 recites "about fifteen minutes". "About" would include times less than 15 minutes. And, depending on one's point of view, 40 minutes could be considered "about fifteen minutes", which is also outside the supported range.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-7, 10-19, 30, 38, 42 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Butland et al (USPN 6,030,657, prior art of record) in view of Eichen et al (WO 99/57550, prior art of record) and Anderson et al (USPN 6,168,948 B1).

With regard to claim 1, Butland teaches nucleic acid taggants for preventing product diversion and counterfeiting (see entire document, especially abstract and columns 3-5). In particular, the method comprises *recovering a nucleic acid containing taggant sample from an item, wherein the taggant sample potentially contains one or more target nucleic acids* (column 5, lines 1-5; column 6, lines 20-25).

With regard to claim 2, Butland teaches adding "junk DNA" to the taggant (see column 8, line 58-64).

With regard to claim 3, Butland teaches DNA molecules of 80-100 base pairs in length, which "comprises 10-30 nucleotides (column 5, lines 60-61).

With regard to claim 4, Butland teaches DNA and RNA (e.g. column 5-6; column 4, lines 66-67).

With regard to claim 7, Butland teaches encapsulating the taggant in a matrix (e.g. casein; column 2, lines 47-54).

With regard to claim 13, Butland teaches encapsulating the nucleic acid in a material that is resistant to the environment (column 2, lines 47-54).

With regard to claim 14, Butland teaches removal of the label for identification (column 4, line 66 through column 5, line 7).

With regard to claim 15, Butland teaches ink (column 2, lines 47-54).

With regard to claim 16, Butland teaches printing (i.e. labeling objects with an ink; column 1, line 64 through column 2, line 6).

With regard to claims 17-19, Butland teaches removing the label from a shirt, which means the taggant sample was applied to a fabric. Butland then teaches applying the taggant sample removed from the shirt to nylon. See column 5, lines 1-7.

With regard to claim 45, Butland teaches that multiple different nucleic acids may be used (column 4, lines 6-30).

With regard to claims 1, 38 and 42, Butland does not teach providing a plurality of reactant chambers and a detection chamber, or the particular detection technology

claimed, i.e. connecting capture probes to electrically separated conductors, and detecting the presence of the target nucleic acid by bridging the gap between them. Butland also does not teach storing reactants in chambers or pumping reactants from the reactant chambers to the detection chamber.

With regard to claims 5 and 6, Butland does not teach capture probes.

With regard to claim 10, Butland does not teach contacting the capture probes with ligase.

With regard to claims 11 and 12, Butland does not teach applying a conductive material such as gold or silver.

With regard to claims 30 and 45, Butland does not teach a plurality of pairs of separated electrical conductors, each pair having attached capture probes that are complementary to a different target.

With regard to claim 1, Eichen teaches:

providing a detection unit comprising…at least one detection chamber…having one or more sets of electrically separated electrical conductor pairs (see for example page 7, lines 24-27)*, each conductor having an attached capture probe such that a gap exists between the capture probes of a pair of electrically separated conductors* (see for example page 7, lines 27-30 and figure 10A)*, wherein the capture probes for each pair of separated electrical conductors are complementary to one of the target nucleic acids* (see page 11, lines 3-5 and figure 10A)*; contact[ing] the sample with the reactants* (for example, "Step 5: Hybridization and stringency wash" beginning at line 26, page 54) *and establish[ing] conditions effective to permit any target nucleic acid present in the …*

sample to bind to the capture probes, thereby connecting the capture probes (see page 8, lines 3-6, page 41, line 18 through page 42, line 11, and figure 10A)*; and detecting any target nucleic acid present in the … sample by determining whether electricity is conducted between the electrically separated conductors* (for example, see page 8, lines 6-15).

With regard to claim 5, Eichen teaches capture probes of 12 nucleotides each (see page 41, line 18 through page 42, line 11).

With regard to claim 6, Eichen teaches capture probes which are DNA (see page 41, line 18 through page 42, line 11).

With regard to claim 10, Eichen teaches ligation (page 30, lines 20-23) and teaches washing at elevated temperatures to remove unbound nucleic acids and ensure high selectivity in duplex formation (page 31, lines 1-4; page 46, lines 28-30; page 55, lines 10-14).

With regard to claim 11, Eichen teaches applying a conductive material over the complex formed by the capture probes and target nucleic acid (page 8, lines 17-20).

With regard to claim 12, Eichen teaches silver (page 41, line 12 through page 42, line 2).

With regard to claims 30 and 45, Eichen teaches a device having a plurality of sites for detecting different targets (see page 19, lines 11-22). It would have been obvious to detect these targets simultaneously as recited in claim 45 in order to save time.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention of the instant application was made to apply the nucleic acid detection method taught by Eichen to detecting nucleic acids used as taggants as taught by Butland. Butland teaches that once the DNA message (mDNA) has been recovered, it could be decoded using a DNA hybridization probes to detect the presence of particular sequences (column 6, lines 20-30). This is essentially what Eichen's technique does: detects a target sequence by hybridizing to probes. One would have been motivated to do use Eichen's method because Eichen teaches at the bottom of page 11 that his method is "highly sensitive, allowing the formation of a conductive bridge even where few, or even a single complex between a recognition moiety and a target is formed between, or on the electrodes of an assay set."

With regard to claims 1, 38 and 42, the use of reagent (reactant) reservoirs, waste reservoirs and pumping systems to move fluids between such reservoirs and reaction chambers was well-known in the field of nucleic acid analysis devices. For example, Anderson teaches:

> A variety of analysis operations may generally be performed, including size based analysis using, e.g., microcapillary electrophoresis, and/or sequence based analysis using, e.g., hybridization to an oligonucleotide array. In addition to the various reaction chambers, the device will generally comprise a series of fluid channels which allow for the transportation of the sample or a portion thereof, among the various reaction chambers. Further chambers and components may also be included to provide reagents, buffers, sample manipulation, e.g., mixing, pumping, fluid direction (i.e., valves) heating and the like. (column 5, lines 52-63)
>
> In certain aspects, the central chamber may have a dual function as both a hub and a pumping chamber. In particular, this central pumping chamber can be fluidly connected to one or more additional reaction and/or storage chambers and one or more analytical chambers. (paragraph bridging columns 24-25)
>
> As described previously, reagents used in each operation integrated within the device may be exogenously introduced into the device…Alternatively, the reagents may be disposed within storage chambers adjacent to and fluidly connected to their respective

> reaction chambers, whereby the reagents can be readily transported to the appropriate chamber as needed. (paragraph bridging columns 37-38)

With regard to claim 38, Anderson also teaches waste reservoirs (column 24, lines 15-40).

The concepts of storing reagents in reagent chambers, storing waste in waste reservoirs, and pumping reagents to and waste from reaction (analysis, detection) chambers, are such fundamental concepts of bioanalytical devices that such cannot be considered as basis for patentability. One would have been motivated to modify the method suggested by the combination of Butland and Eichen to include such steps because this was generally understood in the art of bioanalytical devices.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Butland et al (USPN 6,030,657, prior art of record) in view of Eichen et al (WO 99/57550, prior art of record) and Anderson et al (USPN 6,168,948 B1) as applied to claims 1-7, 10-19, 30, 38, 42 and 45 above and further in view of Stone (USPN 5,512,436, prior art of record) and McMahon et al (USPN 5,310,650, prior art of record).

The teachings of Butland, Eichen and Anderson have been discussed. Furthermore, Eichen teaches addition of Denhardt's solution to the sample containing the DNA to be detected (page 54, lines 28-30).

Butland, Eichen and Anderson do not teach selecting a matrix material from the group consisting of the recited compounds.

As evidenced by McMahon et al (column 9, lines 50-55), Denhardt's solution contains polyvinyl pyrrolidone and is a preferred blocking agent for hybridization assays.

Stone teaches that polyethylene glycol and polyvinyl alcohol are notable examples of hybridization rate enhancers (column 3, lines 30-33).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention of the instant application was made to include compounds such as polyvinyl pyrrolidone, polyethylene glycol or polyvinyl alcohol in the matrix containing the nucleic acid taggant in the combined teachings of Butland, Eichen and Anderson, since these compounds were known in the art to enhance nucleic acid hybridization, which is a critical component of the detection method taught by Eichen.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Butland et al (USPN 6,030,657, prior art of record) in view of Eichen et al (WO 99/57550, prior art of record) and Anderson et al (USPN 6,168,948 B1) as applied to claims 1-7, 10-19, 30, 38, 42 and 45 above and further in view of Connolly (USPN 6,248,529 B1).

The teachings of Butland, Eichen and Anderson have been discussed.

Butland, Eichen and Anderson do not teach contacting the capture probes with nucleases.

Eichen's method is based on hybridizing a target nucleic acid to two capture probes, thus providing a continuous filament upon which a conductive metal is deposited so as to establish an electrical circuit connecting two electrodes (see rejection of claim 1 above).

Connolly teaches methods for using nucleic acids to form a circuit by depositing, for example, metals thereon: "The negatively charged backbone of a nucleic acid

molecule can be used to attract and attach materials necessary to form circuit elements. Metals, doped metals, and other materials can be specifically bound to exposed regions of a DNA molecule" (column 11, lines 16-20).

Connolly also teaches: "The method of manufacturing a circuit element may further consist of disrupting or removing the DNA template from the circuit or a portion thereof. Nucleic acid molecules have intrinsic electric properties, which may interfere with the functioning of certain circuit elements. One may take into account the electrical properties of the nucleic acid molecule in the design of the element. Where it is not possible to incorporate the intrinsic properties of the nucleic acid molecule into the circuit element, it may be preferred to disrupt or remove the nucleic acid molecule or a portion of the molecule" (column 3, lines 57-67, emphasis provided).

Finally, Connolly teaches: "Once a material is deposited on the nucleic acid molecule, the nucleic acid molecule can be disrupted and/or removed by using treatments which will specifically disrupt the nucleic acid molecule but not affect the circuit elements. Nucleic acid molecules can be disrupted, or possibly removed, by treating the circuit with nucleases, ionizing radiation, oxidizing compounds" (column 13, lines 5-11).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to modify the method taught by the combined teachings of Butland, Eichen and Anderson to add a step of nuclease treatment after the metal deposition (and hence, after the "contacting" step), in order to remove the nucleic acid

because Connolly teaches that nucleic acids have intrinsic electrical properties that may interfere with the functioning of circuits made in this manner.

Claims 24-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Butland et al (USPN 6,030,657, prior art of record) in view of Eichen et al (WO 99/57550, prior art of record) and Anderson et al (USPN 6,168,948 B1) as applied to claim 17 above and further in view of Benardelli (USPN 5,020,831, prior art of record).

The teachings of Butland, Eichen and Anderson have been discussed. These references do not teach using the DNA taggant on cardboard packaging containing the item to be identified.

Benardelli teaches a method of tagging an item with a latent label for purposes such as certification and prevention of counterfeiting (see claim 1). Benardelli teaches applying the tag to packaging (see claim 1). Benardelli teaches the package can be cardboard (column 7, lines 9-13 and figure 6; column 4, line 64 through column 5, line 2).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention of the instant application was made to apply the DNA taggant taught by Butland to cardboard packaging containing the item to be identified, since Benardelli demonstrates that cardboard packaging was known in the art as a location for latent indicia for purposes of authentication and counterfeit-prevention, which is the precise purpose of the DNA taggants taught by Butland (see entire document, especially abstract and columns 3-5).

Claims 1-6, 10-12, 15-21, 28-30, 38, 42 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bancroft et al (USPN 6,312,911 B1, prior art of record) in view of Eichen et al (WO 99/57550, prior art of record) and Anderson et al (USPN 6,168,948 B1).

With regard to claim 1, Bancroft teaches a method of authenticating an object by tagging it with a hidden DNA (see, for example, abstract and column 1, lines 8-15). The method includes *recovering a nucleic acid containing taggant sample from an item, wherein the taggant sample potentially contains one or more target nucleic acids* (e.g. column 12, lines 2-5).

With regard to claim 2, Bancroft teaches addition of random DNA (column 3, lines 4-18).

With regard to claim 3, Bancroft teaches, for example, DNA of 50-150 nucleotides, which "comprises" 10-30 nucleotides (e.g. column 12, lines 29-32).

With regard to claim 4, Bancroft teaches DNA (e.g. column 12, lines 29-32).

With regard to claims 15 and 16, Bancroft teaches ink (column 10, lines 40-45).

With regard to claims 17-21, Bancroft teaches applying the DNA taggant to tags made of paper, plastic, nitrocellulose, nylon or fabric (column 7, lines 23-27). Bancroft teaches applying the DNA taggant to articles of clothing (column 10, lines 13-15).

With regard to claims 28 and 29, Bancroft teaches using the DNA taggant to authenticate pharmaceuticals in either liquid or solid forms (column 10, lines 20-25).

With regard to claim 45, Bancroft teaches "at least one secret DNA molecule" (e.g. claim 7). "At least one" implies embodiments of more than one, which would be "multiple".

With regard to claims 1, 38 and 42, Bancroft does not teach providing a plurality of reactant chambers and a detection chamber, or the particular detection technology claimed, i.e. connecting capture probes to electrically separated conductors, and detecting the presence of the target nucleic acid by bridging the gap between them. Bancroft also does not teach storing reactants in chambers or pumping reactants from the reactant chambers to the detection chamber.

With regard to claims 5 and 6, Bancroft does not teach capture probes.

With regard to claim 10, Bancroft does not teach contacting the capture probes with ligase.

With regard to claims 11 and 12, Bancroft does not teach applying a conductive material such as gold or silver.

With regard to claims 30 and 45, Bancroft does not teach a plurality of pairs of separated electrical conductors, each pair having attached capture probes that are complementary to a different target.

With regard to claim 1, Eichen teaches:

providing a detection unit comprising…at least one detection chamber…having one or more sets of electrically separated electrical conductor pairs (see for example page 7, lines 24-27)*, each conductor having an attached capture probe such that a gap exists between the capture probes of a pair of electrically separated conductors* (see for

example page 7, lines 27-30 and figure 10A), *wherein the capture probes for each pair of separated electrical conductors are complementary to one of the target nucleic acids* (see page 11, lines 3-5 and figure 10A)*; contact[ing] the sample with the reactants* (for example, "Step 5: Hybridization and stringency wash" beginning at line 26, page 54) *and establish[ing] conditions effective to permit any target nucleic acid present in the … sample to bind to the capture probes, thereby connecting the capture probes* (see page 8, lines 3-6, page 41, line 18 through page 42, line 11, and figure 10A)*; and detecting any target nucleic acid present in the … sample by determining whether electricity is conducted between the electrically separated conductors* (for example, see page 8, lines 6-15).

With regard to claim 5, Eichen teaches capture probes of 12 nucleotides each (see page 41, line 18 through page 42, line 11).

With regard to claim 6, Eichen teaches capture probes which are DNA (see page 41, line 18 through page 42, line 11).

With regard to claim 10, Eichen teaches ligation (page 30, lines 20-23) and teaches washing at elevated temperatures to remove unbound nucleic acids and ensure high selectivity in duplex formation (page 31, lines 1-4; page 46, lines 28-30; page 55, lines 10-14).

With regard to claim 11, Eichen teaches applying a conductive material over the complex formed by the capture probes and target nucleic acid (page 8, lines 17-20).

With regard to claim 12, Eichen teaches silver (page 41, line 12 through page 42, line 2).

With regard to claims 30 and 45, Eichen teaches a device having a plurality of sites for detecting different targets (see page 19, lines 11-22). It would have been obvious to detect these targets simultaneously as recited in claim 45 in order to save time.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention of the instant application was made to apply the nucleic acid detection method taught by Eichen to detecting nucleic acids used as taggants as taught by Bancroft. One would have been motivated to do use Eichen's method because Eichen teaches at the bottom of page 11 that his method is "highly sensitive, allowing the formation of a conductive bridge even where few, or even a single complex between a recognition moiety and a target is formed between, or on the electrodes of an assay set."

With regard to claims 1, 38 and 42, the use of reagent (reactant) reservoirs, waste reservoirs and pumping systems to move fluids between such reservoirs and reaction chambers was well-known in the field of nucleic acid analysis devices. For example, Anderson teaches:

> A variety of analysis operations may generally be performed, including size based analysis using, e.g., microcapillary electrophoresis, and/or sequence based analysis using, e.g., hybridization to an oligonucleotide array. In addition to the various reaction chambers, the device will generally comprise a series of fluid channels which allow for the transportation of the sample or a portion thereof, among the various reaction chambers. Further chambers and components may also be included to provide reagents, buffers, sample manipulation, e.g., mixing, pumping, fluid direction (i.e., valves) heating and the like. (column 5, lines 52-63)
>
> In certain aspects, the central chamber may have a dual function as both a hub and a pumping chamber. In particular, this central pumping chamber can be fluidly connected to one or more additional reaction and/or storage chambers and one or more analytical chambers. (paragraph bridging columns 24-25)

> As described previously, reagents used in each operation integrated within the device may be exogenously introduced into the device…Alternatively, the reagents may be disposed within storage chambers adjacent to and fluidly connected to their respective reaction chambers, whereby the reagents can be readily transported to the appropriate chamber as needed. (paragraph bridging columns 37-38)

With regard to claim 38, Anderson also teaches waste reservoirs (column 24, lines 15-40).

The concepts of storing reagents in reagent chambers, storing waste in waste reservoirs, and pumping reagents to and waste from reaction (analysis, detection) chambers, are such fundamental concepts of bioanalytical devices that such cannot be considered as basis for patentability. One would have been motivated to modify the method suggested by the combination of Bancroft and Eichen to include such steps because this was generally understood in the art of bioanalytical devices.

Claims 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bancroft et al (USPN 6,312,911 B1, prior art of record) in view of Eichen et al (WO 99/57550, prior art of record) and Anderson et al (USPN 6,168,948 B1) as applied to claims 1-6, 10-12, 15-21, 28-30, 38, 42 and 45 above and further in view of Ryan (USPN 5,982,282, prior art of record).

The teachings of Bancroft, Eichen and Anderson have been discussed. These references do not say anything about the label being tamper proof.

Ryan teaches a tamper proof device (i.e. a label) for verifying the authenticity of merchandise (see column 1, lines 5-10 and figure 1). Ryan teaches the housing of the device is molded plastic (column 2, lines 44-45). Ryan teaches the device contains a bar-code (i.e. it is a bar-code label; column 3, lines 3-13). Ryan teaches the device

contains an authentication element such as DNA (column 4, lines 39-41). Ryan teaches the device is tamper proof (column 3, lines 54-64).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention of the instant application was made to use a tamper proof device comprising DNA as taught by Ryan in the method of verifying authenticity of an item using a DNA taggant as suggested by the combination of Bancroft, Eichen and Anderson. One would have been motivated to use a tamper proof device as taught by Ryan in order to prevent a counterfeiter or other malefactor from altering or discovering the DNA taggant.

Claim 43 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bancroft et al (USPN 6,312,911 B1, prior art of record) in view of Eichen et al (WO 99/57550, prior art of record) and Anderson et al (USPN 6,168,948 B1) as applied to claims 1-6, 10-12, 15-21, 28-30, 38, 42 and 45 above and further in view of Heller et al (USPN 5,849,486).

The teachings of Bancroft, Eichen and Anderson have been discussed. These references do not teach *displaying results* as recited in claim 43.

With regard to claim 43, Heller teaches displaying results to a user on a monitor (column 7, lines 14-15).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to display results when practicing the method suggested

by the combined teachings of Bancroft, Eichen and Anderson, so that whomever was conducting the assay would know what the result was.

Claim 44 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bancroft et al (USPN 6,312,911 B1, prior art of record) in view of Eichen et al (WO 99/57550, prior art of record) and Anderson et al (USPN 6,168,948 B1) as applied to claims 1-6, 10-12, 15-21, 28-30, 38, 42 and 45 above and further in view of Kopf-Sill (US 2001/0020589 A1).

The teachings of Bancroft, Eichen and Anderson have been discussed. These references do not teach programming the detection unit to transfer reactants into the detection chamber as recited in claim 44.

With regard to claim 44, Kopf-Sill teaches that a computer can be programmed to direct fluid transport (paragraph [0041]).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to program a computer to control fluid movement when practicing the method suggested by the combined teachings of Bancroft, Eichen and Anderson, as this would have allowed a user to set up a "walk-away" assay, allowing the user to perform other tasks. Such automation was common in the art, as shown by Kopf-Sill's teachings.

Claim 43 is rejected under 35 U.S.C. 103(a) as being unpatentable over Butland et al (USPN 6,030,657, prior art of record) in view of Eichen et al (WO 99/57550, prior

art of record) and Anderson et al (USPN 6,168,948 B1) as applied to claims 1-7, 10-19, 30, 38, 42 and 45 above and further in view of Heller et al (USPN 5,849,486).

The teachings of Butland, Eichen and Anderson have been discussed. These references do not teach *displaying results* as recited in claim 43.

With regard to claim 43, Heller teaches displaying results to a user on a monitor (column 7, lines 14-15).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to display results when practicing the method suggested by the combined teachings of Butland, Eichen and Anderson, so that whomever was conducting the assay would know what the result was.

Claim 44 is rejected under 35 U.S.C. 103(a) as being unpatentable over Butland et al (USPN 6,030,657, prior art of record) in view of Eichen et al (WO 99/57550, prior art of record) and Anderson et al (USPN 6,168,948 B1) as applied to claims 1-7, 10-19, 30, 38, 42 and 45 above and further in view of Kopf-Sill (US 2001/0020589 A1).

The teachings of Butland, Eichen and Anderson have been discussed. These references do not teach programming the detection unit to transfer reactants into the detection chamber as recited in claim 44.

With regard to claim 44, Kopf-Sill teaches that a computer can be programmed to direct fluid transport (paragraph [0041]).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to program a computer to control fluid movement when

practicing the method suggested by the combined teachings of Butland, Eichen and Anderson, as this would have allowed a user to set up a "walk-away" assay, allowing the user to perform other tasks. Such automation was common in the art, as shown by Kopf-Sill's teachings.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SAMUEL WOOLWINE whose telephone number is (571)272-1144. The examiner can normally be reached on Mon-Fri 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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scw

/Young J Kim/
Primary Examiner, Art Unit 1637